UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

PAUL SCHILF and CYNTHIA SCHILF, as special administrators for the ESTATE OF PETER RAYMOND SCHILF, Deceased and PAUL SCHILF and CYNTHIA SCHILF, Individually,	)	
Plaintiffs,	)	
vs.	)	No. 4:07-cv-04015-LLP
ELI LILLY AND COMPANY and, QUINTILES TRANSNATIONAL CORPORATION,	)	
Defendants.	)	

BRIEF IN SUPPORT OF
MOTION TO ALTER OR AMEND JUDGMENT

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I. Introduction

F.R.Civ.P. 59(e) allows a court to alter or amend a judgment. It "was adopted to clarify a district court's power to correct its own mistakes in the time period immediately following entry of judgment." *Innovative Home Health Care v. P.T.-O.T. Assocs.*, 141 F.3d 1284, 1286 (8th Cir. 1998). The Court's Memorandum Opinion and Order Granting Summary Judgment misunderstands the critical facts. With great respect, Plaintiffs ask the Court to correct its mistake and deny Defendants' motion for summary judgment.

II. The Court misunderstood the facts

The Court properly assumed, for purposes of deciding the summary judgment motion, that Lilly's warnings before the black box warning were inadequate because they "do not convey a causal connection between taking Cymbalta and suicidality."[1] The Court's assumption is consistent with the FDA's October 15, 2004 Advisory, which states: "Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders."[2] The same document, under the boldfaced heading **"WARNINGS-Clinical Worsening and Suicide Risk,"** states: "A causal role for

[1]Doc. 276 p. 5.

[2]Doc. 141-7 p. 2.

antidepressants in inducing suicidality has been established in pediatric patients."[3] Nonetheless, the Court granted summary judgment for Defendants based on what it erroneously believed were two undisputed facts.

First, the Court ruled that before Dr. Briggs prescribed Cymbalta to Peter Schilf, Dr. Briggs "was aware of the same warnings that Plaintiffs now say Defendants should have given to prescribing physicians such as Dr. Briggs. Thus, a warning from Defendants would not have informed Dr. Briggs of anything he did not already know." Second, the Court stated that Dr. Briggs testified unambiguously that "he would prescribe Cymbalta for Peter Schilf given adequate warnings," and that Plaintiffs "did not discredit or call into question this testimony."[4]

As Plaintiffs will show, the Court was incorrect on both these critical matters. The record establishes the opposite of what the Court stated. Likewise, the court was incorrect that Dr. Briggs read the 2004 FDA press release, and incorrect that Plaintiffs admitted that he read it. Plaintiffs respectfully ask the Court to correct its ruling, and re-set the case for trial.

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[3]Doc. 141-7 p. 2.

[4]Doc. 276 p. 6.

A. Dr. Briggs was not aware—even at his 2006 deposition—of a causal connection between Cymbalta and suicidality, or of the Cymbalta clinical trial suicides that he would have wanted to know about

Even at his 2006 deposition, Dr. Briggs never admitted that there was a causal connection between Cymbalta and suicidality. To the contrary, he testified that no causal link between Cymbalta or any other antidepressant had been established:

- Dr. Briggs testified that he knew in 2004 that the FDA "indicated that recent studies have been evaluated and as a result there *may be an increased association* with antidepressants and suicide ideations and gestures."[5]
- Dr. Briggs thought that the FDA had *not* found any increased risk of suicidality: "They *weren't* saying the risk was there. They're saying, based on those studies, you know, these were the differences."[6]
- Dr. Briggs testified that in October, 2004, *the increased risk in taking antidepressants and suicide was "unknown."* He was

[5]Doc. 274-1 (Dr. Briggs Depo.) page 76 (emphasis added). Each page of doc. 274-1 has three numbers: the court reporter's original page number, the condensed transcript page number, and the electronically-affixed court file page number. This brief uses the court reporter's original page number.

[6]Doc. 274-1 p. 84 (emphasis added).

asked: "What did you understand the increased risk—back in October of 2004, a month before Peter Schilf came to see you, what was your understanding of the increased risk in taking antidepressants and suicide?" He answered: "*I think it was unknown at that time based on the information available.*"[7]

- When Dr. Briggs was asked specifically whether he "understood" the FDA study, his answer was totally opaque: "In the context of how the studies were interpreted."[8]
- Asked at his deposition "As we sit here today, do you think there's an increase in suicide risk when taking antidepressants?," he answered "I think *it remains to be seen*, yeah."[9]

Likewise, even at his deposition, Dr. Briggs was unaware of the Cymbalta clinical trial suicides, but would have liked to know about them:

- He was asked: "Are you aware, as we sit here today, whether there were any suicides that had occurred during the clinical trials

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[7]Doc. 274-1 p. 84-85 (emphasis added).

[8]Doc. 274-1 p. 85.

[9]Doc. 274-1 p. 103 (emphasis added). He gave the same testimony at p. 104 line 2-7.

of Cymbalta?" He answered: "I don't know the details of any suicides, no."[10]

- He was asked: "Whether those clinical trials were for depression or something else, you're not aware of any suicides that took place in any clinical trials for Cymbalta; is that how I am to understand your testimony?" He answered: "Yeah, I don't recall any."[11]
- He was asked whether he would have wanted to know about suicides during Cymbalta clinical trials before prescribing Cymbalta, and answered that he would "like to see the information."[12]
- He had not heard of Tracy Johnson, who committed suicide during one of the Cymbalta trials.[13]

Lilly admits the clinical trial suicides. Lilly's Amended Answer ¶ 10 states: "there were suicide attempts and at least four deaths of clinical trial patients for which

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[10]Doc. 274-1 p. 93.

[11]Doc. 274-1 p. 93.

[12]Doc. 274-1 p. 94.

[13]Doc. 274-1 p. 133.

suicide was the suspected manner of death during the time such patients were enrolled in Lilly-sponsored duloxetine [Cymbalta] clinical trials."[14] Lilly does not deny that Tracy Johnson committed suicide during a Cymbalta clinical trial, instead Lilly says that it isn't allowed to answer the allegation.[15]

In short, Dr. Briggs was completely unaware, both when he prescribed Cymbalta for Peter Schilf in 2004, and when he testified in 2006, of what the Court properly assumed as true in deciding the summary judgment motion: that a causal connection exists between taking Cymbalta and suicidality. So the Court was incorrect that Lilly "would not have informed Dr. Briggs of anything he did not already know" if Lilly had warned Dr. Briggs of a causal connection between Cymbalta and suicidality.[16] And Dr. Briggs' testimony that he would have liked to know about the Cymbalta clinical trial suicides underscores the importance of this information to him as a prescribing physician.

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[14]Doc. 55 p. 4.

[15]Doc. 55 p. 5.

[16]Doc. 276 p. 6.

B. Dr. Briggs did not testify, unambiguously or otherwise, that he would have prescribed Cymbalta for Peter Schilf had he been given adequate warnings

The Court's opinion states that Dr. Briggs testified unambiguously that "he would prescribe Cymbalta for Peter Schilf given adequate warnings," and that Plaintiffs "did not discredit or call into question this testimony."[17] With respect, the Court was incorrect.

Dr. Briggs was never asked whether he would have prescribed Cymbalta for Peter Schilf had he been "adequately warned" of its risks. Nor was he ever asked to answer a hypothetical question whether he would have prescribed Cymbalta for Peter Schilf had he known of the clinical trial suicides, or had he known of a causal link between Cymbalta and suicidality, or had Lilly done what Plaintiffs allege in the First Amended Complaint that it should have done.[18]

In ruling that Dr. Briggs testified unambiguously that "he would prescribe Cymbalta for Peter Schilf given adequate warnings," and that Plaintiffs "did not discredit or call into question this testimony," the Court quoted Dr. Briggs' answer "Yes" to a leading question from Lilly's attorney. The question was: "I believe

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[17]Doc. 276 p. 6.

[18]Doc. 53 ¶¶ 17-21.

you've already testified that, sitting here today, you still believe that your decision to prescribe Cymbalta for Peter Schilf was appropriate, correct?"[19]

It does not follow, either logically or by inference, that because Dr. Briggs still believes that his decision to prescribe Cymbalta for Peter Schilf was correct, he also would have prescribed it had he been given adequate warnings. *No* evidence exists as to whether Dr. Briggs would have prescribed Cymbalta for Peter Schilf had Lilly told him about a causal link between Cymbalta and suicidality; or had Lilly told him about the suicides in the Cymbalta trials; or had Lilly sent him a "Dear Health Care Professional" letter about suicidality like the one that Wyeth, the only other manufacturer of an SNRI medication, distributed in 2003; or had Lilly done what Plaintiffs allege in the First Amended Complaint that it should have done.[20]

Wyeth's 2003 letter warned of "important safety information on the use of venlafaxine [Effexor] in children and adolescents." Wyeth warned: "In clinical studies of pediatric patients (ages 6 to 17), efficacy was not established for major depressive disorder," and that "there were increased reports among those patients on Effexor XR, vs. placebo, of hostility and suicide-related adverse events, such as suicidal ideation and self-harm." Wyeth warned that "Effexor and Effexor XR have

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[19]Doc. 274-1 p. 112.

[20]Doc. 53 ¶¶ 17-21.

not been and are not now recommended for use in pediatric patients."[21] Plaintiffs' First Amended Complaint alleged that Lilly failed to warn adequately by failing to issue such a letter.[22]

As Plaintiffs showed above, even at his deposition Dr. Briggs was not aware of a causal link between Cymbalta and suicidality, or the Cymbalta clinical trial suicides. Nothing in his testimony suggests what he would have done had he known matters in 2004 that he still didn't know when he testified.

To the contrary, Dr. Briggs' testimony, and the reasonable inferences from it, show that these facts would have made a difference to him, as they would have to any physician. Because of the FDA suicidality study, Dr. Briggs did not prescribe Prozac. In prescribing Cymbalta, he chose what he understood as "the next generation Prozac," which was not part of the suicidality study.[23] In short, *Dr. Briggs' belief that there was no connection between Cymbalta and suicidality caused him to choose Cymbalta rather than Prozac or another antidepressant*. And when asked whether he would have liked to know about suicides in the Cymbalta clinical trials, he twice made it clear that his answer is "yes":

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[21]Doc. 144-16.

[22]Doc. 53 p. 9 ¶ 19.

[23]Doc. 274-1 p. 30.

> Q. If it turns out that there were some suicides that occurred during clinical trials of Cymbalta, you would have wanted to know about that prior to prescribing Cymbalta, wouldn't you, doctor?
>
> A. *I'd like to see the information*.
>
> Q. I just want to be clear. If it turns out, if there's some evidence at some point that comes forward that during the clinical trials of Cymbalta that there were suicides, that's something that you would have liked to have known about prior to prescribing Cymbalta?
>
> A. *I would like to see the information, yeah.*[24]

Regardless of whether an objective or subjective test is used, the issue is whether the manufacturer adequately warned the physician of the dangers of the medication, and whether the physician (or if an objective test is used, a reasonable physician) would still have prescribed the drug if he knew then what he knows now—not whether the physician still believes that his decision to prescribe the drug in the past, based on what he knew then, was correct. The cases the Court cited in its opinion granting summary judgment illustrate this point. *Ehlis v. Shire Richwood, Inc.*, 367 F.2d 1013, 1018-19 (8th Cir. 2004), applying North Dakota law, found that

[24]Doc. 274-1 p. 94 (objections and colloquy between lawyers omitted, emphasis added).

the physician stated that the warnings were adequate, and knew the risks of prescribing the medication. The physician had read the Physicians' Desk Reference and double-blind studies, and had talked to pharmacy representatives. No evidence existed that the manufacturer had failed to disclose information that the physician wanted, and no evidence existed of the other failures alleged by the Schilfs in their First Amended Complaint. The court stated that the physician continued to prescribe the medication, but this was just one fact in the case, not a controlling fact—and by contrast, Dr. Briggs could not remember whether he prescribed Cymbalta for a pediatric patient after Peter Schilf's suicide.[25]

In *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1019 (10th Cir. 2001), applying Oklahoma law, the treating physician testified that she would have prescribed the same medication, even had she known the information contained in the warning that the Plaintiffs argued that Defendant should have given. There is no such testimony here. In *Stafford v. Wyeth*, 411 F.Supp.2d 1318, 1322 (W.D. Okla. 2006), applying Oklahoma law, the physician testified that "knowing all the side effects and risks, he still would have prescribed the medication for the Plaintiff." Here, the record shows that even at his 2006 deposition, Dr. Briggs did not know of a causal connection

[25]Doc. 274-1 p. 111.

between Cymbalta and suicidality, did not know of the Cymbalta clinical trial suicides, and would have liked to know of them.

When Dr. Briggs was asked "If you had to do it over again, Doc, would you prescribe him Cymbalta," he answered "Well, you can't go over again. There's no going back, so to say that—I wish things—obviously, I wish things would have been different."[26] Only later did Lilly ask him the leading question whether he still believes that his decision to prescribe Cymbalta was appropriate. His equivocal answer on direct examination undercuts his later agreement with Lilly's leading question, and raises a question of fact for the jury.

The Court's decision quotes Dr. Briggs' negative answer to the question "Have you made a conscious decision based on the black box warning not to use Cymbalta in a teenage patient under 18," then the Court says: "Dr. Briggs testified that the subsequent inclusion of a black box warning regarding suicide in the FDA-approved Cymbalta prescribing information has not changed his analysis of the benefits and risks of Cymbalta for teenage patients."[27] With respect, Dr. Briggs gave no such testimony.

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[26]Doc. 274-1 p. 68.

[27]Doc. 276 p. 5.

Dr. Briggs testified about risks and benefits of Cymbalta in response to three questions. First, he answered "yes" to a leading question about Cymbalta generally, which did *not* address whether Cymbalta is appropriate for pediatric patients: "do you still believe that Cymbalta has a favorable risk-benefit profile for the treatment of major depressive disorder?"[28] Second, he testified that risks and benefits of a medication can change based on a patient's body size.[29] Third, he testified that he did not do a risk-benefit analysis in prescribing Cymbalta for Peter Schilf, and that his earlier reference to a risk-benefit analysis referred to "the medication in general" and whether it is a "good medication" meaning whether it is "efficacious."[30]

None of these three answers speak to whether Dr. Briggs' risk-benefit analysis of Cymbalta for use with juveniles has changed or would change based on the black box warning or anything else. And Plaintiffs' case is not predicated solely on the absence of the black box warning or the information in it. Plaintiffs alleged that Lilly failed to adequately warn physicians.[31] Dr. Briggs' lack of knowledge, even at his 2006 deposition, of a causal connection between Cymbalta and suicidality, or of the

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[28]Doc. 274-1 p. 111-12.

[29]Doc. 274-1 p. 114.

[30]Doc. 274-1 p. 131.

[31]Doc. 53 ¶¶ 17-21.

Cymbalta clinical trial suicides that he would have wanted to know about, at least creates an issue of fact as to whether Lilly adequately warned physicians such as Dr. Briggs.

C. The Court was incorrect that Dr. Briggs "was aware of the same warnings that Plaintiffs now say Defendants should have given to prescribing physicians such as Dr. Briggs"

The Court's opinion says that the warnings "that Plaintiffs now say Defendants should have given to prescribing physicians such as Dr. Briggs" are identical to what Dr. Briggs knew. With respect, the Court was incorrect. The warnings that Plaintiffs say that Defendants should have given to prescribing physicians such as Dr. Briggs—and the misrepresentations that Defendants made instead—are set out in Plaintiffs' First Amended Complaint.[32] Plaintiffs alleged that Defendants failed to educate Dr. Briggs properly about the risks of Cymbalta, causing Dr. Briggs to be unable to advise Peter and Cynthia Schilf properly.[33]

Unless a drug manufacturer adequately warns physicians, the learned intermediary doctrine does not apply. *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004) ("The learned intermediary doctrine states that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription

[32]Doc. 53 ¶¶ 17 to 23.

[33]Doc. 53 ¶¶ 33 to 35.

products to warn ultimate consumers directly.") Lilly did not adequately warn Dr. Briggs of the Cymbalta clinical trial deaths that he would have wanted to know about, nor did it adequately warn him of a causal link between Cymbalta and suicidality. Nor is there any evidence that Lilly did what Plaintiffs' First Amended Complaint alleges that it failed to do.[34]

D. Defendants failed to rebut the heeding presumption

The Court stated: "Even if this Court were to predict that the South Dakota Supreme Court would adopt the heeding presumption and apply it in a prescription drug case involving the learned intermediary doctrine, Defendants are entitled to summary judgment because they have rebutted the presumption with Dr. Briggs' unequivocal testimony that he still believes Cymbalta was appropriate for Peter Schilf."[35]

As Plaintiffs showed above, Dr. Briggs was not aware, even at his deposition, of a causal connection between Cymbalta and suicidality, or of the Cymbalta clinical trial suicides. He did not testify that he would have prescribed Cymbalta to Peter Schilf had he been adequately warned. And he was not aware of the warnings that Plaintiffs say that Defendants should have given to prescribing physicians.

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[34]Doc. 53 ¶¶ 17 to 21.

[35]Doc. 276 p. 8.

The Court quoted *Thom v. Bristol-Myers Squib Co.*, 353 F.3d 848, 856 (10th Cir. 2003) for the principle that "the defendant can rebut the presumption through testimony that a different warning would not have made a difference in the actions of the physician."[36] But as Plaintiffs have shown above, there is no evidence whether a different warning would have made a difference in Dr. Briggs' decision whether to prescribe Cymbalta to Peter Schilf, so Defendants have not rebutted the heeding presumption.

E. The Court was incorrect that Dr. Briggs "read all about" the "upcoming black box warnings," and incorrect that Plaintiffs "admit that Dr. Briggs read the FDA announcement"

The Court stated: "Plaintiffs admit that Dr. Briggs read the FDA announcement," and that "Dr. Briggs read all about those warnings in the FDA press release prior to seeing Peter Schilf."[37] Whether Dr. Briggs read the FDA press release of October 15, 2004, is not critical to Plaintiffs' case. Even if he read it, the matters set out above would still preclude summary judgment for Defendants. But the Court was incorrect, both as to whether Plaintiffs admit that Dr. Briggs read the FDA announcement, and whether he did so.

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[36]Doc. 276 p. 8.

[37]Doc. 276 p. 5-6.

Lilly asked Dr. Briggs if he was "familiar" in the fall of 2004 "that the FDA had issued some press releases about antidepressants."[38] He said he was.[39] Lilly then asked: "I think you testified you became aware that 2004—I think it was an October 2004 FDA press release. You became aware of that shortly after it came out?"[40] Actually, the 2004 FDA press release had *not* come up at Dr. Briggs' deposition before this question, so Dr. Briggs had *not* testified that he was aware of it. Nonetheless, Dr. Briggs answered—inaccurately—"That's correct."[41] And even though he was inaccurate, he was only agreeing that he was "aware" of it, not that he had read it.

Lilly asked Dr. Briggs: "And you saw it at that time?" Dr. Briggs answered: "Yeah, *without being specific, I was aware that it was in the media, either the television or print media, radio*."[42] Undeterred by Dr. Briggs' testimony that he could not be "specific," and was only "aware that it was in the media, either the television or print media, radio," Lilly asked Dr. Briggs: "Before you prescribed Cymbalta for

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[38]Dr. Briggs Depo. p. 117.

[39]Dr. Briggs Depo. p. 117.

[40]Dr. Briggs Depo. p. 117.

[41]Dr. Briggs Depo. p. 118.

[42]Dr. Briggs Depo. p. 118 (emphasis added).

Peter Schilf on November 26, 2004, had you seen and become aware of the FDA's press release regarding antidepressants in pediatric populations and the issue of suicidality?" He answered "Yes."[43]

The most reasonable reading of Dr. Briggs' testimony is that he was "aware" that the FDA press release was "in the media," and can't be specific whether it was on television, in print, on the radio, or in some combination of them. This reading is consistent with his earlier testimony that in the fall of 2004, the issue of antidepressants and suicide was "in the lay press . . . on the news, radio, televisions, all those."[44] *After* that testimony, Lilly asked Dr. Briggs whether he had "seen and become aware of" the FDA's press release, and he answered "Yes."[45] The inference that he had "seen" it on television or in a newspaper is at least equally as plausible as the inference that he had "seen" the document itself. And even if he had "seen" the document itself, he never testified that he read it.

In their motion for summary judgment, Defendants attempted to transmute Dr. Briggs' testimony into the erroneous finding that he read the press release. Defendants' Statement of Undisputed Material Facts In Support of Their Motion for

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[43]Dr. Briggs Depo. p. 118.

[44]Dr. Briggs Depo. p. 80.

[45]Dr. Briggs Depo. p. 118.

Summary Judgment on Plaintiffs' Failure to Warn Claims (doc. 124) ¶ 22 alleges: "Before he prescribed Cymbalta for Defendant, Dr. Briggs *read* an October 15, 2004 FDA press release, 'FDA Launches a Multi-Pronged Strategy to Strengthen Safeguards for Children Treated With Antidepressant Medications,' regarding the issue of suicidality in pediatric patients treated with an antidepressant." (emphasis added) In support of this allegation, Lilly cited the same page of Dr. Briggs' deposition quoted above.[46]

Plaintiffs responded: "Dr. Briggs actually testified he had 'become aware' of it, he did not say he had read it." Plaintiffs then stated, still in response to Lilly's ¶ 22: "There is reason to believe that Dr. Briggs was mistaken in this recollection." In support of this statement, Plaintiffs cited and quoted the testimony of Cynthia Schilf, as well as other testimony of Dr. Briggs.[47] Plaintiffs never admitted that Dr. Briggs read the FDA press release. While there is evidence that he became "aware" of it, there is no evidence that he read it. And the record does not establish what parts he was "aware" of and what parts he was not "aware" of.

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[46]Doc. 124 ¶ 22, quoting Dr. Briggs Depo. p. 118.

[47]Doc. 144 ¶ 22.

F. Summary

The Court was incorrect that Dr. Briggs "was aware of the same warnings that Plaintiffs now say Defendants should have given to prescribing physicians such as Dr. Briggs. Thus, a warning from Defendants would not have informed Dr. Briggs of anything he did not already know."[48] To the contrary, the record establishes that Dr. Briggs was not aware of a causal link between Cymbalta and suicidality, nor was he aware of the Cymbalta clinical trial suicides, and that he would have wanted to know about such suicides. And the Court found, for purposes of the summary judgment motion, that Lilly's warnings before the black box warning were inadequate because they did not convey a causal connection between Cymbalta and suicidality. So Dr. Briggs was not aware of what the Court found as a fact for purposes of the summary judgment motion.

Likewise, the Court was incorrect in stating that Dr. Briggs testified that "he would prescribe Cymbalta for Peter Schilf given adequate warnings." Dr. Briggs did not so testify. The Court also was incorrect that Dr. Briggs "read all about" the "upcoming black box warnings," and incorrect that Plaintiffs "admit that Dr. Briggs read the FDA announcement." As a result, and with respect, the Court's grant of

[48]Doc. 276 p. 6.

summary judgment was based on an incorrect understanding of the facts, and should be altered or amended.

III. A reasonable jury could find that Lilly committed deceit by suppressing information of completed suicides during the Cymbalta clinical trials

The Court ruled: "Plaintiffs' deceit claim under SDCL 20-10-2(3) also must fail because it is completely subsumed by their failure to warn claims. In their Amended Complaint, Plaintiffs alleged that 'suppression of information concerning completed suicides during the Cymbalta clinical trials is deceitful within the meaning of the statute.' First Amended Complaint at ¶ 42. The Court is not aware of any evidence in the record to support this claim."[49]

For two reasons, Plaintiffs are entitled to trial on their deceit claim. First, if the Court agrees that Plaintiffs are entitled to trial on their failure to warn claim, the deceit claim rises with the failure to warn claim, just as it fell with it. Second, the Court is incorrect that there is no evidence in the record to support Plaintiffs' claim. Lilly admits that four completed suicides occurred during its Cymbalta clinical trials. Doc. 55 p. 10 ("Lilly admits that there were suicide attempts and at least four deaths of clinical trial patients for which suicide was the suspected manner of death during the time such patients were enrolled in Lilly-sponsored duloxetine clinical trials.")

[49]Doc. 276 p. 8.

If the Court's statement that it "is not aware of any evidence in the record to support this claim" refers to whether Lilly's failure to adequately warn physicians of the four suicides and the still-undisclosed number of suicide attempts was significant, the evidence is that it was significant to Dr. Briggs—he testified that he did not know of any suicides in the Cymbalta clinical trials, and that he would have liked to know of any such suicides.[50] By inference, he would also have wanted to know about suicidal behavior that did not result in completed suicide. He testified that he prescribed Cymbalta rather than Prozac or another antidepressant because of questions about the connection of Prozac with suicide.[51] He read that Cymbalta was "going to really be the next generation Prozac with fewer side effects."[52]

In light of these facts, a reasonable jury could find that Lilly did not adequately warn physicians of the Cymbalta clinical trial suicides, and suicidal behavior that did not result in completed suicides, and that reasonable physicians, including Dr. Briggs, needed this information to make informed decisions about whether to prescribe Prozac, Cymbalta, or some other medication to depressed young people. Dr. Briggs wanted information about Lilly clinical trial suicides, but he didn't receive an

[50]Doc. 274-1 p. 93, 94, 103, and 104.

[51]Doc. 274-1 p. 30.

[52]Doc. 274-1 p. 30.

adequate warning of it from Lilly or anyone else in time to take it into account in deciding what medication to prescribe for Peter Schilf. Dr. Briggs based his decision on what medication to prescribe in part on whether there was a connection between the medication and suicidality. He knew of no causal connection between Cymbalta and suicidality. Nor did he believe that the FDA drew a connection between antidepressants (including Cymbalta) and suicide. A reasonable jury could compare the FDA Public Health Advisory of October 15, 2004 (doc. 134-16), that warns of the increased risk of suicidality in children and adolescents treated with Cymbalta and other antidepressants, with Lilly's failure to adequately disclose its Cymbalta clinical trial multiple suicides, and other suicidality that did not result in completed suicide, and find that Lilly suppressed facts that it should have disclosed.

IV. Conclusion

Genuine disputed issues of material fact preclude summary judgment on Plaintiffs' failure to warn and deceit claims. The Court erred in granting summary judgment for Defendants. Plaintiffs ask the Court to grant their motion to alter or amend the judgment, to deny Defendants' motion for summary judgment, and to restore the case to its status before judgment was entered for Defendants.

Dated: November 9, 2010

Respectfully submitted,

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Certificate of Service

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Pursuant to Local Rule 7.1.B.1., I certify that this brief contains 5,119 words, according to the word count of the word-processing system that I used to prepare it.

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